INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Brooks Rehabilitation Clinical Research Center / "Effect of Neuro20 Functional Electrical Stimulation Suit on Autonomic Function, Muscle Performance, and Gait"**
Principal Investigator:	**Mark Bowden, PT, PhD**
Telephone:	**(352) 318-2779 (24-Hour)**
Address:	**Brooks Rehabilitation Clinical Research Center** **3901 University Blvd S** **Suite 101** **Jacksonville, FL 32216**

KEY INFORMATION

You are invited to take part in a research study. Your permission is needed in order to partake in the study. This research aims to understand the effect of the Neuro20 Functional Electrical Stimulation Suit on autonomic nervous system function, muscle performance, and gait after amputation or neurologic injury. The clinical care you receive will not be affected whether you choose to participate in this study or not.

If you choose to participate in this study, you will complete up to 12 sessions using the Neuro20 Suit. All sessions will be no more than 2 hours and will take place at Brooks Rehabilitation. You will also complete assessments before you start using the suit and after you have completed all training sessions. Each assessment session will last no more than four hours. Assessments will include assessments of walking, muscle performance and autonomic nervous system function. Additionally, you will complete questionnaires on demographic information, quality of life, participation and use of the suit.

Take your time understanding what is being asked of you and ask the study staff as many questions about the study as you would like. The study staff can explain words or information that you do not understand. Reading this form and talking to the study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form.

BACKGROUND AND PURPOSE

You are being asked to participate in this study because you have a diagnosis of amputation or neurologic injury and are able to provide Informed Consent. You are unable to participate in the study if you have a pacemaker or defibrillator, active cancer, pregnancy, uncontrolled seizures or seizure within the last 6 months, implanted stimulator or pump that cannot be turned off externally, significant, active wounds in areas stimulated by the suit or an inability to follow a three-step motor command.

The purpose of this research study is to study the effect of the Neuro20 Functional Electrical Stimulation Suit on autonomic function, muscle performance, and walking ability. Electrical stimulation is intended to stimulate muscles in order to improve muscle performance. The Neuro20 is approved for this use by the United States Food and Drug Administration. In this study, the use of the device is considered investigational. Twenty subjects will participate in this study.

WHAT WILL HAPPEN DURING THE STUDY?

You will complete two assessment sessions and up to twelve study treatment sessions with the suit. The study will be conducted at Brooks Rehabilitation.

Before any study-related procedures are performed, you will be asked to read and sign this consent document. Then the following will happen:

<u>Assessments</u>:

You will complete assessments with a study therapist measuring:

- Walking ability
    - 10-meter walk test: You will complete several trials of walking a 10-meter distance while being timed.
    - Timed up-and-go: You will complete two trials of standing up from a chair, walking a distance of three meters, turning around, walking back to the chair and sitting down.
    - 6-minute walk test: You will walk for six minutes covering as much ground as you can in that time.
- Muscle performance and range of motion
- Autonomic function, including measuring your heart rate and response to light flashes
- Functional near-infrared spectroscopy during gait: You will wear a head device that generates infrared light to measure activity in your brain while you walk
- H reflex measurement: This test measures the reactions of your muscle after an electrical stimulation. The investigator will introduce an electrical current into the back of your knee and will measure how your calf muscle reacts

A study therapist will be with you throughout the walking assessments, and you will be able to use any support needed. You are also able to rest whenever needed.

You will also be guided through questionnaires examining:

- Demographic information
- Injury classification and function
- Quality of life
- Participation

Interventions:
You will complete up to 12 sessions using the Neuro20 suit under the direct supervision of study staff. Each session will be 1-2 hours in duration. Each session, you will change into the suit and then receive no more than 105 minutes of electrical stimulation, and then change out of the suit and have a skin check. The suit has 20 electrodes that will stimulate muscles in your upper arm (above the elbow), upper leg (above the knee), chest, abdominals, and back. Stimulation levels will be adjusted to your comfort. You will likely feel tingling and/or muscle contractions. The timing and intensity of each type of activity will depend on your individual needs and will be prescribed by the study doctor:

- Strength: You will perform strength training exercises or specific tasks with electrical stimulation from the suit
- Conditioning: The electrical stimulation from the suit will be used to get your body used to electrical stimulation and increase your nervous system's control
- Cool down: The suit will provide electrical stimulation to aid in active recovery from the training
- Massage: The suit will provide electrical stimulation to massage muscles and improve circulation
- Patterned movements: The suit will provide electrical stimulation to improve muscle performance as you perform specific movements and/or tasks

Vital signs (such as heart rate and blood pressure) and symptoms will be monitored throughout. Any adverse responses (side effects) will be immediately addressed (for example, using a lower stimulation intensity, turning stimulation off, etc.) and reported to the investigator who will advise on continued participation in the study. Repeated and unresolved adverse responses will lead to withdrawal from the study.

EXPECTATIONS
If you participate in this study, you will be expected to complete the following sessions within 6 months:

- Complete up to 12 interventions sessions
- Complete pre, mid, and post intervention assessments

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS
There are minimal risks to participating in this study.

Exercise: You may feel some muscle soreness consistent with exercise within the rehabilitation setting. This will be mitigated by a gradual increase to stimulation time and intensity. For

example, your first session will include no more than 20 minutes of “strength” mode stimulation, and the “strength” stimulation time will increase by no more than 20 minutes each visit.

The Neuro 20 suit: You may also have minor skin irritation from using the study device, which will be monitored. You may feel tingling, burning, or muscle contractions or muscle cramping as a result of the electrical stimulus from the suit. If you feel burning or pain from the suit, tell your study doctor/study staff immediately.

The stimulation suit may be uncomfortable and may have an effect on heart rate, heart rhythm, and blood pressure, which will also be monitored throughout each visit.

The Neuro20 suit should not be used in anyone who has an implanted metallic or electronic device because it could cause electric shock, burns, or electrical interference. Let your study doctor know if you have any implanted devices. Additionally, the Neuro20 device should not be used over areas prone to bleeding or over the abdomen or low back during menstruation as the stimulation may temporarily increase menstrual flow.

Functional Near Infrared Spectroscopy: You may have minor discomfort from wearing the head device. You may have minor skin irritation from the light used in the device.

H reflex measurement: You may experience pain or discomfort from the electrical stimulation. The electrodes placed on your skin could cause skin irritation. The area of your leg may need to be shaved for the electrodes to work correctly.

Questionnaires: The questionnaires used in this study may be upsetting. You do not need to answer any questions that you are not comfortable with.

You may not participate in this study if you are pregnant or planning to become pregnant. The safety of the study device for use during pregnancy has not been established.

There also may be other risks that are unknown.

PROTECTIONS AGAINST RISK

You will be asked if you have any skin irritation, muscle soreness, or any other medical changes before and after each exercise session. Additionally, the study staff will monitor your skin integrity, vital signs and muscle soreness before, during, and after each session. All symptoms will be closely monitored by study staff and adjusted immediately to your comfort.

It is important that you promptly tell the investigator or study staff if you believe you have been injured because of taking part in this study. You can tell the investigator or study staff in person or call the investigator at the number provided on page one of this form.

NEW FINDINGS
Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

ALTERNATIVES TO PARTICIPATION
This study is for research purposes only. The alternative is to not participate in this study and continue with your usual care that you are currently receiving. By choosing not to participate, your care will not be altered in any way.

BENEFITS
You may or may not benefit as a result of your participation in this study. There is the possibility of improved autonomic regulation (i.e., blood pressure regulation) or improved muscle performance (i.e., increased muscle strength or decreased hypertonicity). There is, however, no guarantee that you will benefit from your participation in this study. Information learned from the study may help other people in the future by assisting in understanding the Neuro20 suit and how it may be used after injury

COMPENSATION FOR PARTICIPATION
You will not receive any monetary compensation for your participation in this study.

CONFIDENTIALITY
Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

Some persons/agencies may need to see your medical records in order to monitor the research and verify the study data, including the research ethics review board Advarra IRB (an independent ethics committee that reviewed the ethical aspects of this study to help protect the rights and safety of study subjects).

Your study records including confidential information about you collected during the study will be kept at a secure location.

While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy.

By signing this information and consent form, you consent to the collection, access, use and disclosure of your information as described above.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

COMPENSATION FOR INJURY

While we believe the risk of injury during this study is minimal, please be advised that Brooks Rehabilitation will manage your care consistent with the management of all treatment-related adverse events (side effects). You or your insurance will be responsible for any medical cost including deductibles, co-insurance, or co-payments. Any injury requiring medical care will be reported to the Institutional Review Board providing oversight of this study.

It is important that you promptly tell the investigator or study staff if you believe you have been injured because of taking part in this study. You can tell the investigator or study staff in person or call the investigator at the number provided on page one of this form.

COSTS

There will be no charge to you for your participation in this study. The study-related procedures and study visits will be provided at no charge to you or your insurance company.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research subject;
- Eligibility to participate in the study;
- The Investigator's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the Investigator at the telephone number listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00083882.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

The Investigator or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

If you leave the study for any reason, the Investigator may ask you to have some end-of-study tests for your safety.

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing this consent document. I will receive a copy of this signed consent document.

_____

Subject's Printed Name

_____ _____

Subject's Signature Date

_____

Printed Name of the Person Conducting the Consent Discussion

_____ _____

Signature of the Person Conducting the Consent Discussion Date

WITNESS SIGNATURE FOR SUBJECTS WHO CANNOT READ (if applicable)

The study subject has indicated that he/she is unable to read. The consent document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____

Printed Name of Impartial Witness

_____ _____

Signature of Impartial Witness Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study investigator and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.
- Information about mobility and how well you are able to take care of yourself.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of Brooks Clinical Research Center.
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- Governmental agencies of other countries.
- Other research doctors and medical centers participating in this study, if applicable.
- A data safety monitoring board which oversees this study, if applicable.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the study device works and is safe.
- To compare the study device to other devices.
- For other research activities related to the study device.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study investigator at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____

Printed Name of Subject

_____ _____

Signature of Subject Date

_____

WITNESS SIGNATURE FOR SUBJECTS WHO CANNOT READ (IF APPLICABLE)

The study subject has indicated that he/she is unable to read. This Authorization document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____

Printed Name of Impartial Witness

_____ _____

Signature of Impartial Witness Date